General

Guideline Title

Australian clinical practice guidelines: depression and related disorders – anxiety, bipolar disorder and puerperal psychosis – in the perinatal period. A guideline for primary health care professionals.

Bibliographic Source(s)

Austin M-P, Highet N, Guidelines Expert Advisory Committee. Australian clinical practice guidelines for depression and related disorders -- anxiety, bipolar disorder and puerperal psychosis -- in the perinatal period. A guideline for primary health care professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011 Feb. 108 p. [293 references]

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 10, 2016 – Olanzapine : The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Recommendations

Major Recommendations

Grades of recommendation (A-D and good practice point [GPP]) are defined at the end of the "Major Recommendations" field.

For the purposes of these guidelines, 'perinatal' is defined as the period covering pregnancy and the first year following pregnancy or birth.

Effective Care of Mental Health in the Perinatal Period

GPP - Primary and maternity care services should develop locally relevant strategies to ensure that they can provide appropriate, culturally responsive psychosocial care to all women in their communities.

GPP - Involving members of a woman's support network in her care as early as practical provides opportunities for all involved to gain an understanding of the impact of pregnancy and early parenthood on emotional health and well-being. It also enables assessment of psychosocial factors affecting family members and family relationships.

GPP - Psychoeducation for women and, where appropriate, their significant other(s) should be a routine component of care in the perinatal period. This should include discussion of mental health and provision of educational materials (e.g., the *beyondblue Emotional Health During Pregnancy and Early Parenthood* booklet).

GPP - Health professionals should ensure that communication with women in the perinatal period is empathic and non-directive, and that discussions are woman-centred.

C - As a minimum, all health professionals providing care in the perinatal period should receive training in woman-centred communication skills and psychosocial assessment.

GPP - Health professionals involved in managing women's mental health during the perinatal period should seek ongoing support or mentoring.

Psychosocial Assessment

GPP - Clinical judgement is central to decision-making about further support and/or referral, as it informs the interpretation of answers to the psychosocial factor assessment and scores derived from the Edinburgh Postnatal Depression Scale (EPDS).

GPP - As early as practical in pregnancy and 6–12 weeks after a birth, all women should be asked questions around psychosocial domains as part of normal care. If a woman affirms the presence of psychosocial factors, she should be asked whether she would like help with any of these issues.

B - The EPDS should be used by health professionals as a component of the assessment of all women for symptoms of depression in the *antenatal* period.

GPP - Consider a score on the EPDS of 13 or more for detecting symptoms of major depression in the *antenatal* period.

B - The EPDS should be used by health professionals as a component of the assessment of all women in the *postnatal* period for symptoms of depression or co-occurring depression and anxiety.

C - A score of 13 or more can be used for detecting symptoms of major depression in the *postnatal* period.

GPP - Health professionals should be aware that women who score 13 or more on the EPDS may be experiencing anxiety, either alone or co-occurring with depression. Decision-making about further assessment for anxiety should take into account the woman's answers to questions 3, 4, and 5 of the EPDS and her response to the psychosocial assessment question about 'worrying'.

GPP - The non-diagnostic nature of the EPDS, its purpose (identification of women who may benefit from follow-up care) and the fact that it relates to the previous 7 days (not just that day) should be clearly explained to all women by the administering health professional.

GPP - All women should complete the EPDS at least once, preferably twice, in both the *antenatal* period and the *postnatal* period (ideally 6–12 weeks after the birth). Administration of the EPDS can be readily integrated with existing routine antenatal and postnatal care.

GPP - While the EPDS is a self-report tool, in some cases (e.g., difficulties relating to language or literacy, cultural issues, disability), it may be appropriate for it to be administered verbally.

GPP - *For women who score 10, 11, or 12* on the EPDS: administration of the EPDS should be repeated within 2–4 weeks, and existing support services reviewed and increased if needed.

GPP - *For women who score 13 or 14* on the EPDS (once *postnatally* or twice *antenatally*): referral to an appropriate health professional (ideally their usual general practitioner [GP]) should be made.

GPP - *For women with high scores on the EPDS (e.g., 15 or more)*: the administering health professional should ensure access to timely mental health assessment and management.

GPP - *For women who score 1, 2, or 3 on EPDS Question 10*: the administering health professional should assess the woman's current safety and the safety of children in her care, and act according to clinical judgement, seek advice, and/or refer immediately for mental health assessment.

Other Assessments in the Perinatal Period

GPP - Assessing the mother–infant interaction should be an integral part of the care of women in the *postnatal* period.

GPP - Where significant difficulties are observed with the mother–infant interaction and/or there is concern about the mother's mental health, the risk of harm to the infant should be assessed.

GPP - Comprehensive mental health assessment is required for women with reported or observed marked changes in mood, thoughts, perceptions, and behaviours in the early postnatal period.

GPP - Women identified as being at risk of suicide (through clinical assessment and/or the EPDS) should be specifically assessed. Any immediate risk should be managed and support and treatment options considered. Enquiry about the safety of the infant should also be made.

Acting on Psychosocial Assessments

GPP - In cases where comprehensive mental health assessment is required, health professionals should identify referral options and actively encourage and support women to use them.

GPP - Primary care health professionals have an ongoing role in the psychosocial care of women in the perinatal period, whether they provide treatment or refer the woman to a health professional with mental health expertise.

Supporting Emotional Health and Wellbeing in the Perinatal Period

GPP - Women in the perinatal period may benefit from being provided with reliable advice on lifestyle issues and sleep, as well as assistance in planning how this advice can be incorporated into their daily activities during this time.

C - Non-directive counselling in the context of home visits can be considered as part of the management of mild to moderate depression for women in the *postnatal* period.

Psychological Therapies

GPP - Psychological therapies in the perinatal period should be undertaken by registered practitioners with accredited training in the relevant therapy.

GPP - Decision-making about the type of psychological therapy should be based on the woman's preferences, the suitability of a particular therapy to the individual woman, the severity of her disorder and the availability of a suitably trained practitioner.

B - Cognitive behavioural therapy should be considered for treating women with diagnosed mild to moderate depression in the *postnatal* period.

C - Interpersonal psychotherapy can be considered for treating women with diagnosed mild to moderate depression in the *postnatal* period.

D - Psychodynamic therapy can be considered for treating women with diagnosed mild to moderate depression in the *postnatal* period.

GPP - When a woman is experiencing a significant mental health disorder and has difficulties interacting with her infant, both problems need to be addressed. The wellbeing of the infant needs to be considered at all times.

Pharmacological Treatments

GPP - In decision-making about the use of pharmacological treatment in the *antenatal* period, consideration should be given to the potential risks and benefits to the pregnant woman and fetus of treatment versus non-treatment.

GPP - In decision-making about the use of pharmacological treatment in the *postnatal* period, this needs to be weighed against minimal possible exposure to the infant during breastfeeding.

GPP - When the risk of birth defects is discussed, women should be provided with a detailed explanation of the baseline, absolute and relative risks to the fetus or infant of pharmacological treatment, as well as the potential impact on the offspring of treatment versus non-treatment.

Depression during Pregnancy

GPP - If a decision is made to commence or continue antidepressant medication during pregnancy, use of selective serotonin reuptake inhibitors (SSRIs) can be considered as this is the antidepressant category about which most is known. The current evidence on SSRIs shows no consistent pattern of additional risk of birth defects. While the safety of tricyclic antidepressants (TCAs) is supported by a lesser body of evidence, they can also be considered, especially if they have been effective previously.

GPP - If a decision is made to discontinue or decrease antidepressant medication, it is important to gradually taper the dose, closely monitor, and have a plan to identify relapse early.

GPP - Withdrawal symptoms of antidepressants need to be distinguished from symptoms of relapse, therefore close monitoring post discontinuation/reduction is essential. Expert psychiatric advice should be sought if necessary.

GPP - Guidelines for the use of antidepressants in the general population should be consulted (see Appendix 6 of the original guideline document).

Anxiety Disorders during Pregnancy

GPP - Use of benzodiazepines can be considered for short-term treatment of severe anxiety in pregnant women while awaiting the onset of action of an SSRI or TCA. Long-acting benzodiazepines should be avoided as much as possible.

GPP - Guidelines for the use of benzodiazepines in the general population should be consulted (see Appendix 6 of the original guideline document).

Bipolar Disorder during Pregnancy

GPP - Sodium valproate should not be prescribed for bipolar disorder in women of childbearing age. Exposure in pregnancy is associated with an increased risk of major birth defects and adverse cognitive outcomes for the infant.

GPP - If a decision is made to discontinue or decrease a mood stabiliser during pregnancy it is important to closely monitor and have a plan to identify relapse early.

GPP - Clozapine should not be initiated during pregnancy. Wherever possible an alternative antipsychotic should be used for women contemplating pregnancy or already taking clozapine on presentation.

Depression in the Postnatal Period

GPP - Women with healthy full-term infants who plan to breastfeed can be advised that SSRIs are not contraindicated.

Anxiety Disorders in the Postnatal Period

GPP - Use of benzodiazepines can be considered for short-term treatment of severe anxiety in breastfeeding women while awaiting the onset of action of an SSRI or TCA.

Bipolar Disorder and Puerperal Psychosis in the Postnatal Period

GPP - If a decision is made to not recommence a mood stabiliser immediately after the birth, it is important to closely monitor and have a plan to identify relapse early, given the increased risk of relapse at this time.

GPP - The passage of lithium into breast milk is more variable than other psychotropic medications. If the woman chooses to breastfeed, lithium should be used with particular caution. The decision should be made in consultation with a specialist physician and where possible there should be ongoing specialist monitoring for potential adverse effects on the breastfed infant.

GPP - Where possible, clozapine is best avoided in breastfeeding mothers due both to relatively high breast milk concentrations and possible toxic effects for the infant.

GPP - If antipsychotics are prescribed, consideration needs to be given to the woman's physical activity levels and diet to minimise weight gain associated with antipsychotic use.

Definitions:

Definition of Grades of Recommendations

A Body of evidence can be trusted to guide practice

B Body of evidence can be trusted to guide practice in most situations

C Body of evidence provides some support for recommendation(s) but care should be taken in its application

D Body of evidence is weak and recommendation must be applied with caution

Source: *NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines* (NHMRC 2009).

For areas of clinical practice where evidence is lacking or limited, the Guidelines Expert Advisory Committee developed good practice points (GPPs) based on lower quality evidence and clinical consensus.

Clinical Algorithm(s)

The original guideline document includes the following clinical algorithms:

- Acting on identified psychosocial factors
- Appropriate responses to various Edinburgh Postnatal Depression Scale (EPDS) scores
- General responses to identified risk of suicide
- Assessment and care for optimal perinatal mental health

Scope

Disease/Condition(s)

Depression and related disorders, including anxiety, bipolar disorder, and puerperal psychosis in the perinatal period

Note: For the purposes of these guidelines, 'perinatal' is defined as the period covering pregnancy and the first year following pregnancy or birth.

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Nursing

Obstetrics and Gynecology

Pediatrics

Psychiatry

Psychology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Other

Patients

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Guideline Objective(s)

- To provide evidence-based guidance for the early detection and effective management of depression and the related disorders of anxiety, bipolar disorder, and puerperal psychosis for expectant and new mothers
- To improve communication between health professionals and women and their significant other(s)
- To assist health professionals to support women and their significant other(s) in making informed decisions
- To inform education and training of health professionals
- To assist implementation of effective approaches to perinatal mental health care
- To help identify areas for further research

Target Population

Expectant and new mothers with known or suspected depression and/or related disorders of anxiety, bipolar disorder, and puerperal psychosis in the Australian health care setting, including:

- Women who are pregnant, planning a pregnancy, or within the year following birth or being pregnant
- Women with an existing mental health disorder who are pregnant and those who develop a mental health disorder during pregnancy or the postnatal period

Interventions and Practices Considered

1. Staff training in woman-centred communication skills and psychosocial assessment
2. Ensuring that all primary and maternity care services provide effective psychosocial care to all women in their communities
3. Universal psychosocial assessment in the perinatal period
    - Assessment of psychosocial risk factors
    - Assessment for symptoms of depression and anxiety
    - Use of the Edinburgh Postnatal Depression Scale (EPDS)
    - Assessment of mother–infant interaction
    - Assessment of the risk of harm to the infants
    - Comprehensive mental health assessment
    - Assessment of suicide risk
4. Acting on psychosocial assessments (providing treatment or referral)
5. Supporting emotional health and wellbeing in the perinatal period (e.g., providing advice and counselling)
6. Psychological therapies
    - Cognitive behavioural therapy
    - Interpersonal psychotherapy
    - Psychodynamic therapy
7. Pharmacological therapies

- Consideration of benefits and risks of treatment to mother and fetus or infant
- Treatment of depression with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs)
- Short-term use of benzodiazepines for anxiety disorders
- Avoidance of sodium valproate and clozapine during pregnancy and breastfeeding
- Cautious use of lithium during breastfeeding
- Mood stabilizers for bipolar disorder
- Antipsychotic treatment for puerperal psychosis

Major Outcomes Considered

- Incidence of depression and related disorders - anxiety, bipolar disorder, and puerperal psychosis - in the perinatal period
- Risk of depression and related disorders in the perinatal period
- Risk for suicide
- Symptoms of depression and related disorders
- Efficacy/effectiveness of interventions for prevention and treatment of depression and related disorders
- Rate of relapse or recurrence of depression or related disorders
- Sensitivity, specificity, and positive predictive value of assessment tools
- Quality of the mother-infant interaction/relationship
- Physical and mental wellbeing of the woman, fetus/infant, significant others, and family
- Infant outcomes, including obstetric complications, stillbirth, low birth weight, preterm birth, size for gestational age, neonatal adaptation, short- and long-term neurodevelopment, and growth and development outcomes
- Safety of pharmacologic agents in pregnancy and breastfeeding
- Adverse effects of pharmacologic agents
- Cost effectiveness and cost of care

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Research Questions

Research questions were developed by the literature reviewers in consultation with the Guidelines Expert Advisory Committee (GEAC). For a list of research questions, see Appendix 3 of the original guideline document.

Search Strategy

The following mental health disorders were selected for inclusion in this systematic literature review: depression, anxiety disorder, puerperal psychosis, and bipolar disorder. In the context of this review, the term 'perinatal depression and related disorders' refers to these four conditions only.

A systematic method of literature searching and selection was employed in the preparation of this review. Searches were conducted in EMBASE, Medline, PsycINFO, CINAHL, and the Cochrane Database of Systematic Reviews. Searches were not restricted by date.

Research questions related to interventions were addressed by updating the relevant clinical questions from the 2007 National Institute of Health and Clinical Excellence (NICE) antenatal and postnatal mental health systematic review. The NICE review included literature published up until September 2006. Therefore the updated literature search was restricted to literature published from 2006 to July 2009 in order to capture all

literature up to the time of publication.

Search terms were searched for as keywords, exploded where possible, and as free text within the title and/or abstract, in the EMBASE and Medline databases. Variations on these terms were used for the Cochrane library, PsycINFO and CINAHL searches after modifications were made to suit the keywords and descriptors of each search platform.

The reference lists of included papers were reviewed to identify any peer-reviewed evidence that may have been missed in the literature search. Contacting of authors for unpublished research was not undertaken in this review. Conference abstracts were not eligible for inclusion.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Components of Body of Evidence Considered When Grading Each Recommendation

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence base[1]	One or more level I studies with a low risk of bias or several level II studies with a low risk of bias	One or two level II studies with a low risk of bias or a SR/several level III studies with a low risk of bias	One or two level III studies with a low risk of bias, or level I or II studies with a moderate risk of bias	Level IV studies, or level I to III studies/SRs with a high risk of bias
Consistency[2]	All studies consistent	Most studies consistent and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability[3]	Population/s studied in body of evidence are the same as the target population for the guideline	Population/s studied in the body of evidence are similar to the target population for the guideline	Population/s studied in body of evidence differ to target population for guideline but it is clinically sensible to apply this evidence to target population[3]	Population/s studied in body of evidence differ to target population and hard to judge whether it is sensible to generalise to target population
Applicability	Directly applicable to Australian healthcare context	Applicable to Australian healthcare context with few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to Australian healthcare context

Notes: SR = systematic review; several = more than two studies.

[1]Level of evidence determined from the National Health and Medical Research Council (NHMRC) evidence hierarchy

[2]If there is only one study, rank this component as 'not applicable.'

[3]E.g., results in the general population that are clinically sensible to apply to women in the perinatal period

Source: *NHMRC Levels of Evidence and Grades of Recommendations for Developers of Guidelines* (NHMRC 2009).

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Appraisal of Included Studies

Data extraction, critical appraisal, and report preparation was performed by one reviewer and double-checked by another.

Dimensions of Evidence

The aim of the systematic literature review was to find the highest quality evidence to answer the clinical questions being asked. In accordance with National Health and Medical Research Council (NHMRC) guidance, the dimensions of evidence were reviewed for each of the included studies — the value of a piece of evidence is determined by all of these dimensions, not just the level of evidence. The dimensions of evidence considered were level of evidence, quality, statistical precision, size of effect, and relevance of evidence. See Table A3.1 in Appendix 3 of the original guideline document for definitions of each dimension.

Each study was also assigned a level of evidence in accordance with *NHMRC Levels of Evidence and Grades of Recommendations for Developers of Guidelines* (NHMRC 2009). This included the designation of levels of evidence for intervention and diagnostic accuracy studies.

Even within the levels of evidence, there is considerable variability in the quality of evidence. In accordance with NHMRC Levels of Evidence and Grades of Recommendations for Developers of Guidelines, it was necessary to consider the quality of each of the included studies. Quality assessment was based on specific criteria for each study type (systematic review, randomised controlled trial, screening articles using diagnostic criteria, and other trials).

Data Extraction

Abstract review and data extraction was performed in duplicate on a random sample of at least 20% of publications relevant to each clinical question.

Data Synthesis

In addition to the level and quality of evidence of individual studies, the review considered the body of evidence in total. This involved consideration of the volume of evidence and its consistency.

For systematic reviews with analyses involving evidence from randomised controlled trials, a meta-analysis was performed when appropriate using the methodology of the Cochrane Collaboration. However, this was only undertaken if the trial characteristics and patient characteristics were sufficiently homogeneous in order to justify a meta-analysis. Quantitative pooling was not appropriate for other research questions or levels of evidence. Data from observational studies are subject to considerable heterogeneity and to biases that vary between studies.

The review presented the statistical precision of the estimated effect size, together with a discussion of its clinical significance. Finally, the review considered the relevance of the evidence, both with regard to the applicability of the patient population and the intervention, as well as the relevance to the Australian health care setting.

Rating of the Evidence

Rating of the body of evidence involved:

- Review of the evidence base, including the number of studies, level of evidence and quality of studies (risk of bias), and consistency across studies
- Examination of the effect size, the relevance of the evidence base to the research question, and whether the risks and benefits had been considered in terms of clinical impact

- Judgement by members of the Guidelines Expert Advisory Committee of the generalisability of the body of evidence to the target population for the Guidelines and the applicability of the body of evidence to the Australian healthcare context, taking into account feasibility issues (workforce, geographical distance, cost) and existing health care systems

The NHMRC Evidence Statement Form was used for each research question addressed. The form was used as the basis of discussion regarding the key components, which were rated according to the matrix shown in the "Rating Scheme for the Strength of the Evidence" field. Any further notes relevant to developing the recommendation were also recorded in the space provided in the form. The synthesis of the evidence relating to each component was summarised. Any dissenting opinions or other relevant issues were recorded.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Guidelines were developed in accordance with National Health and Medical Research Council (NHMRC) guideline development processes. This involved convening a multidisciplinary committee comprising members with specific expertise in mental health care, as well as representatives of primary care (including general practice, midwifery, maternal and child health, and mental health nursing), consumer organisations and Aboriginal and Torres Strait Islander health care and formal consultation with a wide range of experts, stakeholders, and consumer representatives. A systematic literature review, which identified and critically appraised the evidence based on 26 research questions, provided the basis for the Guidelines. In developing these Guidelines, the Guidelines Expert Advisory Committee (GEAC) also closely examined existing guidelines.

GEAC

The development of the Guidelines has been managed by a GEAC, which was established in 2008. Membership includes consumers, carers, and representatives from perinatal health professions including general practice, maternal and child health nursing, midwifery, rural/remote and Aboriginal and Torres Strait Islander health, psychiatry, obstetrics, and psychology.

Process

The development of the Guidelines has followed the key principles and processes outlined in the document NHMRC Standards and Procedures for Externally Developed Guidelines (see also the "Availability of Companion Documents" field).

The formulation of levels of evidence and grades for recommendations followed the document *NHMRC Additional Levels of Evidence and Grades for Recommendations for Developers of Guidelines*. These are consistent with current NHMRC levels and grades. Consensus by the GEAC on the grading of the systematic literature review (SLR) evidence was achieved for all items and recorded in detailed summary sheets used to form the basis of the GEAC's decisions about what recommendations were appropriate to develop, and the subsequent grading of these recommendations. Where a GEAC member was an author on a paper being assessed, they absented themselves from that GEAC discussion to avoid any potential conflict of interest. Detailed summary sheets documenting these processes were submitted to the NHMRC.

Good practice points (GPPs) were developed to cover areas that had been addressed in the SLR but where insufficient evidence to support a recommendation was identified, as well as areas that were beyond the scope of the SLR but where practical advice is needed. The formulation of GPPs involved a process of:

- Identifying areas where advice was required (e.g., raised by other guidelines, GEAC members or through the consultation process)
- Reviewing any evidence identified through the SLR
- Drafting of a GPP by members with expertise specific to the area
- Refinement of the GPP by the whole GEAC over several iterations until consensus was reached

This process resulted in a range of types of GPP:

- Those informed by the literature review
- Those informed by an additional search on harms from pharmacological interventions undertaken as insufficient information was available on this from the original search
- Those where no specific search was conducted or no evidence was identified but the GEAC determined that GPPs were needed as adjuncts/corollaries of recommendations and/or other GPPs

- Those concerned with principles of care

GPPs were formulated by GEAC members with expertise specific to the area under discussion, and only included in the Guidelines if all GEAC members agreed with the wording.

Throughout this process the GEAC was guided by a Guidelines Assessment Register consultant. The consultant is a perinatal epidemiologist and Co-Director of the Australian Research Centre for Health of Women and Babies at the University of Adelaide. The consultant has an extensive background in evidence-based health care, including preparation of systematic reviews, development of clinical practice guidelines, and translation of research into practice.

Pharmacological Benefits and Harms Workshop — 16 November 2009

There is limited high-quality evidence surrounding the potential harms that may occur with respect to clinical pharmacological treatment for depression, anxiety, and bipolar disorder in the perinatal period and puerperal psychosis.

As the GEAC considered it was most important to discuss the balance of benefits versus potential adverse effects related to pharmacological treatment, a 'Pharmacological Benefits and Harms Workshop' was held as part of the development of the draft Guidelines. Key experts attended the Workshop. The outcomes of this workshop were incorporated into the Guidelines.

Formulating and Grading of Recommendations

Once evidence summaries had been developed, the overall grade of the evidence/recommendation was determined, based on a summation of the rating for each individual component of the body of evidence. Where GEAC members might be considered to have a conflict of interest, they were excluded from voting on the grade of the evidence/recommendation.

NHMRC overall grades of recommendation (see the "Rating Scheme for the Strength of the Recommendations" field) are intended to indicate the strength of the body of evidence underpinning the recommendation. This should assist users of clinical practice guidelines to make appropriate and informed clinical judgements.

Implementing Guideline Recommendations

The guideline implementation strategy was considered at the time that recommendations were being formulated to identify supports required for successful guideline uptake. The questions in the 'implementation of recommendation' section of the NHMRC Evidence Statement Form were used to achieve this purpose. However, in developing recommendations, the GEAC also aimed for best standards — recommendations may be more 'aspirational' and not totally based on the actual implementability. See the "Description of Implementation Strategy" field for more detail.

Rating Scheme for the Strength of the Recommendations

Definition of Grades of Recommendations

A Body of evidence can be trusted to guide practice

B Body of evidence can be trusted to guide practice in most situations

C Body of evidence provides some support for recommendation(s) but care should be taken in its application

D Body of evidence is weak and recommendation must be applied with caution

Source: *NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines* (NHMRC 2009).

For areas of clinical practice where evidence is lacking or limited, the Guidelines Expert Advisory Committee developed good practice points (GPPs) based on lower quality evidence and clinical consensus.

Cost Analysis

Cost-effectiveness of Service Delivery of Perinatal Mental Health Care

The National Perinatal Depression Initiative (NPDI) was informed by key aspects of *beyondblue's National Action Plan for Perinatal Mental Health* (NAP), a coordinated approach that translated into policy and practice the outcomes of a 4-year research project involving 40,000

pregnant women and 12,000 new mothers in 43 health services across Australia.

The development of the NAP included modelling the direct costs of delivering a national program. The NAP estimates included the costs of routine psychosocial assessment and associated workforce training, but not the direct costs of establishing (where necessary) and sustaining recommended primary, secondary, and tertiary pathways to care.

A recent UK study concluded that formal identification methods for detecting depression in the perinatal period do not represent value for money for the UK National Health Service, mainly due to the costs of managing women who are misdiagnosed with depression at a one-off screen who do not subsequently turn out to have depression. This study highlights the need for care to be taken as routine psychosocial assessment is integrated into mainstream perinatal care, to ensure that routine psychosocial assessment is used to identify women who may be at increased risk, but does not lead to misdiagnosis and unnecessary treatment.

Cost Implications of Guideline Recommendations

The prevalence of depression in the postnatal period and the high rate of relapse for bipolar disorder during the postpartum period (see the Introduction in the original guideline document) highlight the importance of identifying women who are experiencing psychosocial factors that increase the likelihood of mental health disorders or symptoms of disorder. The potential costs implicit in identifying women who require additional mental health care in the perinatal period are balanced against the costs of care for these women if early intervention is not provided.

The majority of women who experience depression in the postnatal period receive professional help solely through primary health care services in community settings. A UK report on epidemiology, referral and admission rates found that 2% of women in the postpartum period were referred to psychiatric services and 4 per 1,000 were admitted to a psychiatric unit during the first postnatal year.

Structured psychosocial assessment and use of the Edinburgh Postnatal Depression Scale (EPDS) have been incorporated as a component of routine primary health care in New South Wales (NSW - largest Australian State) for some years. The SAFE START model as articulated in NSW Health's *Families NSW Supporting Families Early Package* ensures that every woman within the NSW public health system who is expecting or caring for a baby is assessed for possible depression and receives at least two psychosocial assessments during the perinatal period. Referrals to specialist mental health services from perinatal psychosocial assessment and depression screening in NSW have been very similar to reports from the UK; that is, between 1% and 3% of women screened in the perinatal period are referred to specialist mental health services. This rate of referral to specialist mental health services has remained fairly steady since implementation of perinatal psychosocial assessment and depression screening in NSW and has been accommodated without undue burden on the mental health system. The primary health care sector (general practitioners/family physicians, midwives, and maternal and child and family care services) has been able to respond to the less severe mental health conditions.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Public Consultation

The draft guidelines were released for a 60-day public consultation, as required in the National Health and Medical Research Council (NHMRC) Act, 1992 (as amended), so that the final guidelines could be submitted for approval by the Chief Executive Officer (CEO) of the NHMRC, under Item 14A *Approval by CEO of guidelines for third parties*, under the Act.

Although the minimum requirement for the public consultation is 30 days, *beyondblue* wished to provide stakeholders and the public with plenty of opportunity to make comments on and suggestions for the draft guidelines, and so a 60-day consultation period was undertaken.

The draft guidelines underwent a rigorous consultation process during which time:

- Interested stakeholders, individuals, and organisations were invited to submit written comments.
- A series of national workshops for consumers and carers and for health professionals was held in capital cities and/or regional centres in each State and Territory.

The public consultation began by way of an advertisement in *The Weekend Australian* of 13 March 2010 and formally ended on 12 May 2010.

Publication Approval

The final Guidelines were submitted to the NHMRC in late 2010. These guidelines were approved by the Chief Executive Officer (CEO) of the NHMRC on 11 February 2011 (with minor amendments approved by the CEO on 17 October 2012), under Section 14A of the NHMRC Act 1992. In approving these guidelines the NHMRC considers that they meet the NHMRC standard for clinical practice guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence is identified and graded for each recommendation (see the "Major Recommendations" field). The recommendations are based on the best available current evidence where this exists, and, where it does not, good practice points (GPPs) are based on lower quality research and clinical expertise.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Early detection and appropriate management of depression and related disorders – anxiety, bipolar disorder, and puerperal psychosis – in the perinatal period
- The recommended guideline approach takes the mother-infant interaction and the broader psychosocial risks for mother, infant, and family into consideration.

Potential Harms

- While approaches to the pharmacological treatment of depression and related disorders during the perinatal period are not likely to differ from approaches at other times, the potential for harm to the fetus and the breastfed infant must be carefully balanced with the harm to mother and offspring if the mother remains untreated. In view of the above, medications should only be prescribed after careful deliberation with the woman (and her significant other[s]), where women are planning a pregnancy, pregnant or breastfeeding. Chapter 8 of the original guideline document discusses the potential harms associated with specific medications — antidepressants, benzodiazepines, anticonvulsants, mood stabilisers, first- and second-generation antipsychotics — and includes points for consideration when discussing their use with women and their significant others. Ongoing monitoring and evaluation will be required, particularly where women are taking other medications for physical conditions.
- In early pregnancy the risks of early pregnancy loss or birth defects are primary concerns in decision-making about the use of psychotropic medications. In later pregnancy the main risk associated with psychotropic medication use is poor neonatal adaptation, which could relate to toxicity or withdrawal following birth and the possibility of long-term impact on the infant's neurodevelopment. Section 8.3 of the original guideline document outlines recent findings on the risks of birth defects, adverse obstetric outcomes, adverse neonatal outcomes and effects on the long-term neurodevelopment of the infant associated with the use of psychotropic medication in pregnancy.
- During breastfeeding many medications taken by the mother are excreted in the milk and ingested by the infant, with consequent concerns about their potential impact on the infant in terms of short-term effects and longer-term neurodevelopment. Breastfed infants whose mothers are taking medication for depression or related disorders should be monitored for side effects of exposure. Where an infant is premature, of low birth weight or ill, use of medications in breastfeeding mothers should be considered with particular care and specialist advice sought. Refer to section 8.4 of the original guideline document for information about specific psychotropic medications used in the postnatal period.
- The passage of lithium into breast milk is more variable than other psychotropic medications. If the woman chooses to breastfeed, lithium should be used with particular caution. The decision should be made in consultation with a specialist physician and where possible there should be ongoing specialist monitoring for potential adverse effects on the breastfed infant.
- Refer also to Table 8.1 in the original guideline document for "Considerations in decision-making about pharmacological treatments in the antenatal period in the Australian context" and Table 8.2 for "Considerations in decision-making about pharmacological treatments in the postnatal period in the Australian context," which summarise the possible benefits to the mother and the possible risks to the pregnancy or

infant of various pharmacological treatments.

Contraindications

Contraindications

- Clozapine should not be initiated during pregnancy. Wherever possible an alternative antipsychotic should be used for women contemplating pregnancy or already taking clozapine on presentation.
- Long-acting benzodiazepines should be avoided as much as possible.
- Sodium valproate should not be prescribed for bipolar disorder in women of childbearing age. Exposure in pregnancy is associated with an increased risk of major birth defects and adverse cognitive outcomes for the infant.

Qualifying Statements

Qualifying Statements

- It should be noted that the good practice points for pharmacologic treatments are based on the best available evidence, up to April 2009 (the cut-off for the systematic literature review). The evidence base changes constantly as new research results emerge. In addition, most studies focus on individual factors and/or medications rather than pharmacological treatments overall. Due to the paucity of evidence, no absolute assurance can be given about any of the medications discussed.
- This publication reflects the views of the authors and not necessarily the views of the Australian Government.
- *Limitations of the evidence*: The Guidelines summarise published evidence based on available high-quality research and make recommendations on key areas of care. As evidence specific to the perinatal period is limited, only a small number of recommendations could be developed. In areas for which there was insufficient research evidence on which to base recommendations, the Guidelines include good practice points (GPPs), which are based on lower quality evidence and/or best-practice clinical judgement. Many GPPs are based on extrapolation of findings from the general population to the perinatal population. The broader depression literature, however, was not reviewed systematically. In the absence of evidence specific to the perinatal period, it is also necessary to refer to guidelines for mental health disorders in the general population.
- *Limitations of the review methodology*: This review used a structured approach to review the literature. However, there are some inherent limitations with this approach. All types of study are subject to bias, with systematic reviews, such as the one conducted here, being subject to the same biases seen in the original studies they include, as well as biases specifically related to the systematic review process. Reporting biases are a particular problem related to systematic reviews and include publication bias, time-lag bias, multiple publication bias, language bias, and outcome reporting bias. A brief summary of the different types of reporting bias is shown in Table A3.3 in Appendix 3 of the original guideline document.
  Some of these biases are potentially present in this review. Only data published in peer-reviewed journals are included. No attempt was made to include unpublished material, as such material typically has insufficient information upon which to base quality assessment, and it has not been subject to the scrutiny of the peer-review process. In addition, the search was limited to English-language publications only, so language bias is also a potential problem. Outcome reporting bias and inclusion criteria bias are unlikely as the reviewers had no detailed knowledge of the topic literature, and the methodology used in the review and the scope of the review was defined a priori.

  The majority of studies included in this review were conducted outside Australia, and therefore, their generalisability to the Australian population and context may be limited. This review was confined to an examination of the efficacy and safety of the interventions and did not consider ethical or legal considerations associated with those interventions.

  The studies were initially selected by examining the abstracts of these articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full text article. However, where detail was lacking, ambiguous papers were retrieved as full text to minimise this possibility.

  The review was conducted over a limited timeframe (December 2008–July 2009). The systematic literature review was conducted sequentially. Cut-off dates for publications included in the review are as follows — models of care: September 2008; tools: January 2009; interventions: March 2009; harms associated with pharmacological treatments: April 2009; community programs, health professional programs, and barriers to interventions: July 2009.

Implementation of the Guideline

Description of Implementation Strategy

Implementation and Review

beyondblue (the Australian non-governmental organization [NGO] that commissioned the clinical practice guideline) will draw upon various processes and channels to widely disseminate the Guidelines and practical guidance for specific groups to the relevant agencies and individuals. This will include health professionals, women and their families, and policy makers involved in influencing perinatal mental health policy and practice. Summaries of the Guidelines and commentaries will also be disseminated.

The Guidelines will be implemented within the context of widespread activity at national, jurisdictional and local level, including national policies (e.g., the Fourth National Mental Health Plan 2009–2014 and the National Agenda for Early Childhood 2007), the *beyondblue* National Action Plan for Perinatal Mental Health (NAP), the National Perinatal Depression Initiative (NPDI), and a range of self-help, support and advocacy services and resources at the local level.

beyondblue is extremely well-placed to instigate and foster communication between the guideline developers and communities of practice and interest in perinatal mental health. *beyondblue* will facilitate implementation of the Guidelines via online channels. These electronic versions will be updated periodically to include higher-level evidence as it becomes available. It is envisaged that a major review of the evidence will be undertaken within 5 years.

Under the NPDI, implementation frameworks will be designed for the main target groups (e.g., midwives, maternal child health nurses, general practitioners [GPs], psychologists), with specific consideration of particular groups such as people living in remote areas and Aboriginal and Torres Strait Islander people.

beyondblue has appointed an independent evaluator to assess the usefulness and uptake of the Guidelines, and to identify changes in clinical practice as a result of the release of the Guidelines.

Implementation

Significant progress is already underway to support the implementation of these Guidelines through the development, support, and implementation of the NPDI (www.mentalhealth.gov.au).

Further implementation of the Guidelines will be supported by the other key elements namely:

- A routine assessment for risk factors for poor emotional health generally or possible depression and related disorders specifically in the perinatal period
- Follow-up support and care for women assessed as being at risk of or experiencing depression and related disorders in the perinatal period
- Workforce development and training for health professionals
- Research and data collection
- Increasing community awareness of perinatal depression

Progress on each of these elements of the National Perinatal Initiative is facilitated through the development and working of several national, State, and Territory working committees. These committees provide an opportunity to collaborate, share information and progress the elements of the NPDI. Continued consultation with key stakeholders, including consumers, carers, and health professionals across all perinatal disciplines will be instrumental in the national dissemination of these Guidelines.

Figure 9.1 of the original guideline document is a pathway for optimal perinatal assessment and care, is adapted from the *National Action Plan for Perinatal Mental Health*, and can form the basis for an integrated system of perinatal mental health care for Australia.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Austin M-P, Highet N, Guidelines Expert Advisory Committee. Australian clinical practice guidelines for depression and related disorders -- anxiety, bipolar disorder and puerperal psychosis -- in the perinatal period. A guideline for primary health care professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011 Feb. 108 p. [293 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Feb

Guideline Developer(s)

beyondblue: the national depression initiative - Nonprofit Organization

Source(s) of Funding

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Ageing under the National Perinatal Depression Initiative (NPDI), which was supported by the Australian Health Ministers' Advisory Council and introduced by the Australian Government in 2008. The NPDI is funded by the Australian ($55 million) and State and Territory governments ($30 million). Under this Initiative, a National Perinatal Depression Framework (2008–09 to 2012–13) was endorsed by the Australian Health Ministers' Conference (AHMC) in November 2009.

beyondblue also acknowledges the support of the National Health and Medical Research Council, which provided and funded a Guidelines Assessment Register (GAR) consultant to support and guide the development of the Guidelines from their inception up until 30 June 2010.

Guideline Committee

Guidelines Expert Advisory Committee (GEAC)

Composition of Group That Authored the Guideline

Committee Members: Professor Marie-Paule Austin (*Chair*), Perinatal Psychiatrist, St John of God Chair of Perinatal and Women's Mental Health (UNSW), NSW; Dr Nicole Highet (*Deputy Chair*), Deputy CEO, *beyondblue*: the national depression initiative, VIC; Professor Anne Buist Director, NE Women's Mental Health, Parent Infant Program, Austin Health, VIC; Ms Lyn Chaplin, Chair, blueVoices, *beyondblue*: the national depression initiative, VIC; Ms Jo Duffy, Consumer representative, WA; Ms Michele Dykman, Perinatal & Infant Mental Health Services, Monash Medical Centre, VIC; Mr Nick Janjic, Proxy carer representative, NSW; Dr Caroline Johnson, Department of General Practice, University of Melbourne, VIC; Dr Sally Lambert, Psychiatry registrar, Hunter New England Area Health Service; Dr Helen Lindner, Senior Manager Membership and Member Groups, Australian Psychological Society, VIC; Ms Rachel Lockey, Midwifery Co-Director Integrated Maternity Services, Department of Health and Families, NT; Ms Philippa Middleton, Guidelines Assessment Register (GAR) consultant from September 2008–June 2010; Professor Jeremy Oats, Chair, Victorian Consultative Council on Obstetric and Paediatric Mortality and Morbidity; Ms Jennie Parham, Principal Network Adviser, Mental Health Australian General Practice Network; Ms Carol Purtell, National Program Manager, Perinatal Depression Initiative, *beyondblue*: the national depression initiative, VIC; A/Prof Jonathan Rampono, Chair Psychological Medicine, King Edward Memorial Hospital, WA; Dr Jan Taylor, Senior Lecturer, Disciplines of Nursing & Midwifery, Faculty of Health, University of Canberra, ACT; Dr Deborah Wiens, Senior Medical Officer, Mater Child and Youth Mental Health Service, QLD

Financial Disclosures/Conflicts of Interest

Managing Conflict of Interest

All members were asked to complete declaration of interest forms prior to acceptance onto the Guidelines Expert Advisory Committee (GEAC), and requested to advise *beyondblue* and the Chair of the GEAC of any competing interests if these arose during the development of the Guidelines; for example, being offered an honorarium to present at a pharmaceutical company event or support (financial or in-kind) to attend conferences, workshops or the like. A review of potential conflicts of interest was undertaken at every committee meeting.

In the case of a member being an author of a paper under discussion, where it could be seen to present a competing interest, particularly in the development of either a recommendation or a good practice point, members were asked to temporarily leave the meeting. This was to avoid the potential for influencing any decision made and was duly recorded in the minutes of the meeting.

The conflict of interest system management process was robust, transparent, and referred to frequently. Apart from the issue of authorship, two conflict of interest issues were identified and discussed:

- Several members of the GEAC disclosed that they had received honoraria and/or funding for research or attendance at conferences from pharmaceutical companies. As no specific pharmaceuticals are being recommended in the Guidelines, the Chair did not consider that such relationships constituted conflicts of interest for the relevant GEAC members.
- One member of the GEAC advised that, prior to being a member of the GEAC, they had served on two separate pharmaceutical company advisory boards. As the relevant member was not a member of any pharmaceutical company advisory board at the same time as being a member of the GEAC, the Chair did not consider that there was any conflict of interest.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the *beyondblue* Web site.

Availability of Companion Documents

The following are available:

- Perinatal clinical practice guidelines – executive summary. A guide for primary care health professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 28 p.
- Management of perinatal mental health disorders. A guide for primary care health professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p.
- Perinatal depression and anxiety. A guide for primary care health professionals. A guide for primary care health professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p.
- Puerperal (postpartum) psychosis. A guide for primary care health professionals. A guide for primary care health professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p.
- Bipolar disorder during pregnancy and early parenthood. A guide for primary care health professionals. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p.
- Perinatal depression and anxiety. Evidence relating to infant cognitive and emotional development. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p.

Electronic copies: Available from the *beyondblue* Web site.

The following are also available:

- NHMRC standards and procedures for externally developed guidelines. 2007 Sep. 21 p. Electronic copies: Available in PDF from the National Health and Medical Research Council (NHMRC) Web site.
- NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. 2009. 23 p. Electronic copies: Available in PDF from the NHMRC Web site.

Sample psychosocial assessment questions and the Edinburgh Postnatal Depression Scale (EPDS) are available in the original guideline document.

Additional resources, including online training and a training matrix, are available from the *beyondblue* Web site.

Patient Resources

The following are available:

- The beyond babyblues guide to emotional health and during pregnancy and early parenthood. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p. Electronic copies: Available in Portable Document Format (PDF) from the *beyondblue* Web site.
- Managing mental health conditions during pregnancy and early parenthood. A guide for women and their families. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p. Electronic copies: Available in PDF from the *beyondblue* Web site.
- Dad's handbook. A guide to the first 12 months. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 4 p. Electronic copies: Available in PDF from the *beyondblue* Web site.
- The beyondblue guide for carers – supporting and caring for a person with depression, anxiety and/or a related disorder. Melbourne (Australia): beyondblue: the national depression initiative; 2011. 40 p. Electronic copies: Available in PDF from the *beyondblue* Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical

questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on May 21, 2013. The information was verified by the guideline developer on June 17, 2013. This summary was updated by ECRI Institute on May 24, 2016 following the U.S. Food and Drug Administration advisory on Olanzapine.

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